REMARKS:

Reconsideration and allowance are respectfully requested.

Claims 1-6, 8-15, and 17-24 are pending in this application. Claims 17-24 have been withdrawn. Accordingly, claims 1-6 and 8-15 are pending and at issue.

In this response, claims 1, 5, 8, and 15 have been amended for further clarification. Support for the amendments can be found in the specification and claims as originally filed. For example, the use of a culture vessel containing at least 500 l of culture medium is disclosed, e.g., in Examples 2 and 3. Relative bioavailability is disclosed at page 24 (final paragraph bridging pages 24-25). Adaptation to grow in suspension culture is disclosed, e.g., at page 15, first paragraph. No new matter is added.

Priority

The Examiner has not agreed that Applicants are entitled to a priority date of October 2, 2000, based on DK PA 2000 01456. The Examiner states, "The broadest reasonable interpretation of 'medium lacking animal-derived components' encompasses medium lacking recombinantly produced components that are naturally expressed in animals. DK PA 2000 0145 fails to disclose a method using medium lacking animal-derived components, wherein the animal-derived components are recombinantly produced components that are naturally expressed in animals." (Office Action at page 2).

Applicants' position is that the present claims encompass the "broadest reasonable interpretation" as proposed by the Examiner. That is, a medium "lacking animal-derived components" means, as stated in the specification of DK PA 200 01456, "[a medium] that contains no protein or other component that was isolated from an animal tissue or an animal cell culture". Applicants do not intend that the claims should also encompass a medium containing "recombinantly produced products that are naturally expressed in animals".

On this basis, the Examiner is again urged to accord the present claims the benefit of the October 2, 2000 filing date of DK PA 2000 01456.

Double Patenting

Claims 1-6, 8-11 and 15 remain rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 8, 10-13 and 15-17 of US Application 10/294,086.

Because the '086 application has not issued, it is respectfully requested that the Examiner allow the present claims to issue and then maintain the rejection in subsequent applications.

Rejections Under 35 U.S.C. §112(second paragraph)

Claims 1-6 and 8-15 have been rejected under 35 U.S.C. §112, second paragraph, for indefiniteness, based on: (i) the phrase "large-scale production" (Claims 1 and 15); (ii) the phrase "pre-determined density" (Claims 1 and 15); (iii) the phrase "animal derived components" (Claims 1 and 15); (iv) the term "bioavailability" (Claims 1 and 15); (v) the phrase "said reference preparation comprises Factor VII produced in the presence of serum" (Claims 1 and 15); (vi) the phrase "suspension culture competent" (Claim 5); and (vii) the phrase "a pre-determined temperature: (Claim 11). These rejections are respectfully traversed.

With respect to the term "large-scale production", in this response claims 1 and 15 have been amended to specify that a large-scale culture vessel contains at least 500 liters of culture medium.

With respect to "pre-determined density", "predetermined temperature", and "Factor VII produced in the presence of serum", it is submitted that those of ordinary skill in the art of cell culture understand the metes and bounds of these terms, and that it would be routine procedure to establish each variable as required by the present claims.

With respect to "animal-derived components", as discussed above, it is submitted that the ordinary meaning of the term encompasses components that are isolated from animal tissues or cells and that this meaning would be recognized by those of ordinary skill in the art.

With respect to "bioavailability", the Examiner's attention is directed to the specification at page 18, first paragraph, which describes in detail how bioavailability is determined and further states: "Relative bioavailability of a test preparation refers to the ratio between the AUC of the test preparation and that of the reference preparation." In this response, claims 1 and 15 are amended to clarify that the relative bioavailability of the test preparation is determined, i.e., compared with a reference preparation that is prepared in parallel.

With respect to "suspension competent", claim 5 is amended herein to require cells that have

been adapted to grow in suspension culture.

Based on the above remarks and amendments, it is respectfully submitted that the claims are definite and that these rejections have been overcome.

Claim 10 has been rejected under 35 USC 112, second paragraph for improper antecedent basis. The Examiner is kindly requested to point out which terms do not have antecedent basis.

Rejections Under 35 U.S.C. §102(b)

Claims 1-3, 5, 6, 8-11 and 15 have been rejected under 35 U.S.C. §102(b) as being anticipated by Reiter et al, 2000 (IDS). The Examiner contends that Reiter et al. discloses expression of Factor VII in CHO cells grown in medium lacking animal-derived components, and states: "The Factor VII-expressing cells are suspension competent, the Factor VII-expressing cells have been adapted to growth in medium lacking animal-derived components (*Example 1*), and/or the maintaining step comprises replacement of medium (*Example 5*)" (Office Action at page 6, emphasis added). Furthermore, the Examiner states: "It is up to Applicants to provide evidence that Factor VII produced using the method of Reiter has functional characteristics that differ from the Factor VII produced by the recited method." (Office Action at page 7.) This rejection is respectfully traversed.

Reiter et al. contains no specific disclosure of production of Factor VII in CHO cells using a serum-free/animal component-free medium. Factor VII is merely one of a long list of proteins cited as possible candidates for production using such a system; is cited only a single time in the patent specification (Reiter et al., column 4, line 44); and is not even included in the subset of so-called "particularly preferred" embodiments (Reiter et al., column 4, lines 47-51). Contrary to the Examiner's implication, Example 1 refers to von Willebrand's Factor, and, notably, Example 5 refers to Factor *VIII*, not Factor VII.

Factor VII and Factor VIII are very different proteins and are not interchangeable; the same applies to Factor VII and von Willebrand's Factor. Reiter et al. thus provides no guidance relating to production of Factor VII; thus, it would be impossible to even contemplate comparing a Factor VII preparation produced by a (non-existent) method of Reiter with one produced by the methods of the present invention.

On this basis, it is respectfully submitted that Reiter et al. does not anticipate the present claims and that this rejection should be withdrawn.

Rejections Under 35 U.S.C. §103(a)

Claims 4 and 11-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Reiter et al., 2000 in view of Chen et al., 1998. With respect to claims 4 and 11, the Examiner contends that Chen et al. discloses transferring a seed culture to a large vessel and cooling the culture prior to sedimentation. With respect to claims 12-14, the Examiner contends that Chen et al. discloses supplementing cultures with glucose. These rejections are respectfully traversed.

As discussed above, Applicants' position is that Reiter et al. does not disclose large-scale culture of Factor VII-producing cells in medium lacking animal-derived components. Furthermore, Rieter et al. fails to provide sufficient guidance to enable one of ordinary skill to achieve the methods of the present invention with any reasonable expectation of success.

Accordingly, it is believed that the presently claimed invention is non-obvious over Reiter et al. and that these rejections should be withdrawn.

In view of the above amendments and remarks, Applicants submit that the application is now in condition for allowance and such action is earnestly solicited.

Applicants believe that no additional fees are due. However, should any fees be due, the Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447. The undersigned invites the Examiner to contact her by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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